

MAR 23 2009

Appendix III 510(k) Summary

As Required by CFR 807.92

The assigned 510(k) Number is: K082439

1. Date Prepared: March 18, 2009;
2. Sponsor
ShanDong WeiGao Group Medical Polymer Co., Ltd
No.312 Shichang Road, Weihai
Shangdong, 264209, China
Contact Person: Ms. Zhao Suxia
Tel: +86-631-5621632
Fax: +86-631-5620555
E-Mail: Zsx9001@sina.com
3. Submission Correspondent
Ms. Diana Hong / Mr. Lee Fu
Shanghai Mid-Link Business Consulting Co., Ltd
Suite 8D, Zhongshan Zhongxin Mansion
No.19, Lane 999, Zhongshan No.2 Road(S)
Shanghai, 200030, China
4. Device Name and Classification:
Device Trade Name: Disposable Angiographic Syringe
Models: CT-200-MA, CT-200A-MA, CT-200B-MA, CT-200+200-MA, CT-200-LF, CT-100-NE,
CT-200-NE, MRI-60+60-MA, MRI-60+110-MA
Device Common Name: Angiographic injector and syringe
Device Classification Name: Injector and syringe, angiographic
Product Code: DXT
Regulation Number: 870.1650
Device Class: II
5. Predicate Device Identification:
ANT Angiographic Syringes
K-number: K072696
6. Intended Use:
Disposable Angiographic Syringe is intended for the injection of contrast media or saline. This syringe is for single use with US legally marketed angiographic injectors.

7. Device Description:

The applicant device of Disposable Angiographic Syringe are plastic, single-use, disposable syringes to be offered in 50/50ml, 50/100mL, 50/200ml, 60/60 mL, 60/100mL, 90mL, 120 mL, 130 mL, 150 mL and 200mL sizes. The syringes will be offered made of PP and PETG both materials, of which, are available in current legally marketed products.

All series follow same design principle, same material, and same intended use. The only differences are volume and the connection (nozzle) to different angiography injector from different manufacturer. The connection differs to fit with US legally Market Angiographic Injectors. The connector difference is only to fit the injector and does not affect the performance of the syringes.

The differences of syringe volume and nozzle type are presented below:

Model (Syringe)	Volume (ml)	Model (Compatible Injectors)
The Disposable Angiographic Syringe models listed below are compatible with the following corresponding Medrad Injector models		
CT-200-MA	200	MCT & MCT Plus CT, Vistron CT, En Vision CT
CT-200A-MA	200	Stellant CT
CT-200B-MA	200	Stellant CT
CT-200+200-MA	200	Stellant CT
MRI-60 60-MA	60/60	Spectris
MRI-60+110-MA	60/110	Solaris
The Disposable Angiographic Syringe model listed below is compatible with the following Libel Flarsheim Injector models		
CT-200-LF	200	CT9000, CT9000ADV
The Disposable Angiographic Syringe models listed below are compatible with the following corresponding Nemoto Kyorindo Injector models		
CT-100-NE	100	Dual Shot CT
CT-200-NE	200	Dual Shot CT

8. Test Conclusion

Laboratory testing was conducted to validate and verify that Disposable Angiographic Syringe met all design specifications and was substantially equivalent to the predicate device.

9. Substantially Equivalent Conclusion:

The subject device, Disposable Angiographic Syringe, is substantially equivalent to the predicate device.



DEPARTMENT OF HEALTH & HUMAN SERVICES

Public Health Service

Food and Drug Administration
9200 Corporate Boulevard
Rockville MD 20850

MAR 23 2009

ShanDong WeiGao Group Medical Polymer Co., Ltd.
c/o Ms. Diana Hong
Suite 8D, No. 19, Lane 999, Zhongshan No. 2 Road(S)
Shanghai, 200030, China

Re: K082439
Disposable Angiographic Syringe
Regulation Number: 21 CFR 870.1650
Regulation Name: Injector and Syringe, Angiographic
Regulatory Class: Class II
Product Code: DXT
Dated: February 26, 2009
Received: February 26, 2009

Dear Ms. Hong:

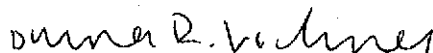
We have reviewed your Section 510(k) premarket notification of intent to market the device referenced above and have determined the device is substantially equivalent (for the indications for use stated in the enclosure) to legally marketed predicate devices marketed in interstate commerce prior to May 28, 1976, the enactment date of the Medical Device Amendments, or to devices that have been reclassified in accordance with the provisions of the Federal Food, Drug, and Cosmetic Act (Act) that do not require approval of a premarket approval application (PMA). You may, therefore, market the device, subject to the general controls provisions of the Act. The general controls provisions of the Act include requirements for annual registration, listing of devices; good manufacturing practice, labeling, and prohibitions against misbranding and adulteration.

If your device is classified (see above) into either class II (Special Controls) or class III (PMA), it may be subject to such additional controls. Existing major regulations affecting your device can be found in the Code of Federal Regulations, Title 21, Parts 800 to 898. In addition, FDA may publish further announcements concerning your device in the Federal Register.

Please be advised that FDA's issuance of a substantial equivalence determination does not mean that FDA has made a determination that your device complies with other requirements of the Act or any Federal statutes and regulations administered by other Federal agencies. You must comply with all the Act's requirements, including, but not limited to: registration and listing (21 CFR Part 807); labeling (21 CFR Part 801); good manufacturing practice requirements as set forth in the quality systems (QS) regulation (21 CFR Part 820); and if applicable, the electronic product radiation control provisions (Sections 531-542 of the Act); 21 CFR 1000-1050. This letter will allow you to begin marketing your device as described in your Section 510(k) premarket notification. The FDA finding of substantial equivalence of your device to a legally marketed predicate device results in a classification for your device and thus, permits your device to proceed to the market.

If you desire specific advice for your device on our labeling regulation (21 CFR Part 801), please contact the Center for Devices and Radiological Health's (CDRH's) Office of Compliance at (240) 276-0120. Also, please note the regulation entitled, "Misbranding by reference to premarket notification" (21CFR Part 807.97). For questions regarding postmarket surveillance, please contact CDRH's Office of Surveillance and Biometrics' (OSB's) Division of Postmarket Surveillance at 240-276-3474. For questions regarding the reporting of device adverse events (Medical Device Reporting (MDR)), please contact the Division of Surveillance Systems at 240-276-3464. You may obtain other general information on your responsibilities under the Act from the Division of Small Manufacturers, International and Consumer Assistance at its toll-free number (800) 638-2041 or (240) 276-3150 or at its Internet address <http://www.fda.gov/cdrh/industry/support/index.html>.

Sincerely yours,





Bram D. Zuckerman, M.D.
Division Director
Division of Cardiovascular Devices
Office of Device Evaluation
Center for Devices and
Radiological Health

Enclosure

Indication for Use

510(k) Number: K082439

Device Name: Disposable Angiographic Syringe

Indications for Use:

Disposable Angiographic Syringe is intended for the injection of contrast media or saline. This syringe is for single use with US legally marketed angiographic injectors.

Prescription Use ✓
(Part 21 CFR 801 Subpart D)

AND/OR

Over-The-Counter Use _____
(21 CFR 801 Subpart C)

(PLEASE DO NOT WRITE BELOW THIS LINE-CONTINUE ON ANOTHER PAGE OF NEEDED)

Concurrence of CDRH, Office of Device Evaluation (ODE)

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Dennis R. Vaughan
(Division Sign-Off)
Division of Cardiovascular Devices

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